

Closing the Loophole: Midwives and the Administration of Vitamin K in Neonates

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In Texas, apprentice midwives do not have prescriptive authority to administer parenteral vitamin K. This case report underscores the importance of parenteral vitamin K administration in preventing vitamin K deficiency bleeding and the potential danger in prohibiting apprentice midwives from providing this standard of care to the newborn. (*J Pediatr* 2009;154:769-71)

Vitamin K acts as a coenzyme in the modification and activation of several coagulation system factors, including factors II (prothrombin), VII, IX, and X.¹ Insufficient vitamin K results in circulation of nonfunctioning vitamin K-dependent proteins in the blood, known as proteins induced by vitamin K absence (PIVKA).^{2,3} Vitamin K deficiency bleeding (VKDB) is classified into 3 subtypes: early, classic, and late. Early VKDB occurs primarily in infants of mothers who have been receiving a vitamin K-blocking medication (eg, an anticonvulsant) and usually occurs within the first 24 hours of life. Classic VKDB occurs between 2 and 7 days of age and often presents with gastrointestinal bleeding. Late VKDB occurs between 2 weeks and 6 months of age. Classic and late VKDB are more prevalent in infants who are breast-fed exclusively, because human milk contains less vitamin K than cow milk.^{3,6}

Although both oral and parenteral vitamin K given at birth prevent early VKDB, only parenteral vitamin K administration consistently prevents the late form of the disease.⁴⁻⁶ The American Academy of Pediatrics recommends that all newborns receive a single vitamin K dose of 0.5 to 1 mg, administered intramuscularly.⁴ This is standard practice in the United States. In Texas, a subset of infants born to apprentice midwives (also known as lay, direct-entry, or licensed midwives) does not receive vitamin K at birth. According to the Texas Midwifery Board's regulations, these practitioners are allowed to administer oxygen and erythromycin ophthalmic ointment prophylaxis but do not have authority to prescribe intramuscular vitamin K. Here we report a tragic case of VKDB in an infant who had been delivered by an apprentice midwife in Texas.

CASE REPORT

The patient was a previously healthy, exclusively breast-fed 6-week-old male infant from Mexico who was transferred to our hospital with intracranial hemorrhage, coagulopathy, and seizures. On arrival to the pediatric intensive care unit, the infant's pupils were fixed and dilated. He underwent endotracheal intubation, required hemodynamic support with dopamine, and was unresponsive to painful stimuli. Neurosurgical intervention was deemed "futile" (Figure). Initial laboratory results were a white blood cell count of 7000/ μ L, hemoglobin value of 18.2 g/dL, platelet count of 143 000/ μ L, INR (international normalized ratio) of 8.3, partial thromboplastin time of 55 seconds, thrombin time of 22 seconds, and fibrinogen level of 221 g/dL. Despite aggressive resuscitation with volume expanders, pressors, fresh frozen plasma, cryoprecipitate, and packed red blood cells, the infant deteriorated and underwent a positive brain death examination within 24 hours.

Initially, nonaccidental trauma was suspected, because the infant also exhibited a gingival hematoma and 2 premorbid bruises on his body. The infant had no signs of liver disease or malabsorption at birth, including jaundice or hypoglycemia. He was growing well, and his mother was a healthy woman who was not taking any medications. The mother reported that she had pointed out the bruises to the infant's health care provider and was told that they were "prominent veins." A skeletal survey was negative for fractures. Records indicated that the infant had been born at a "clinic" on the south Texas border, delivered by an apprentice midwife, and discharged at 8 hours of life. The infant did not receive vitamin K at birth, and the parents were not informed that this was necessary to prevent VKDB.

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The authors declare no conflicts of interest. Submitted for publication Jul 17, 2008; last revision received Oct 23, 2008; accepted Nov 18, 2008.

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0022-3476/\$ - see front matter

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10.1016/j.jpeds.2008.11.038

CNM Certified Nurse Midwife
PIVKA Protein induced by vitamin K absence

VKDB Vitamin K deficiency bleeding

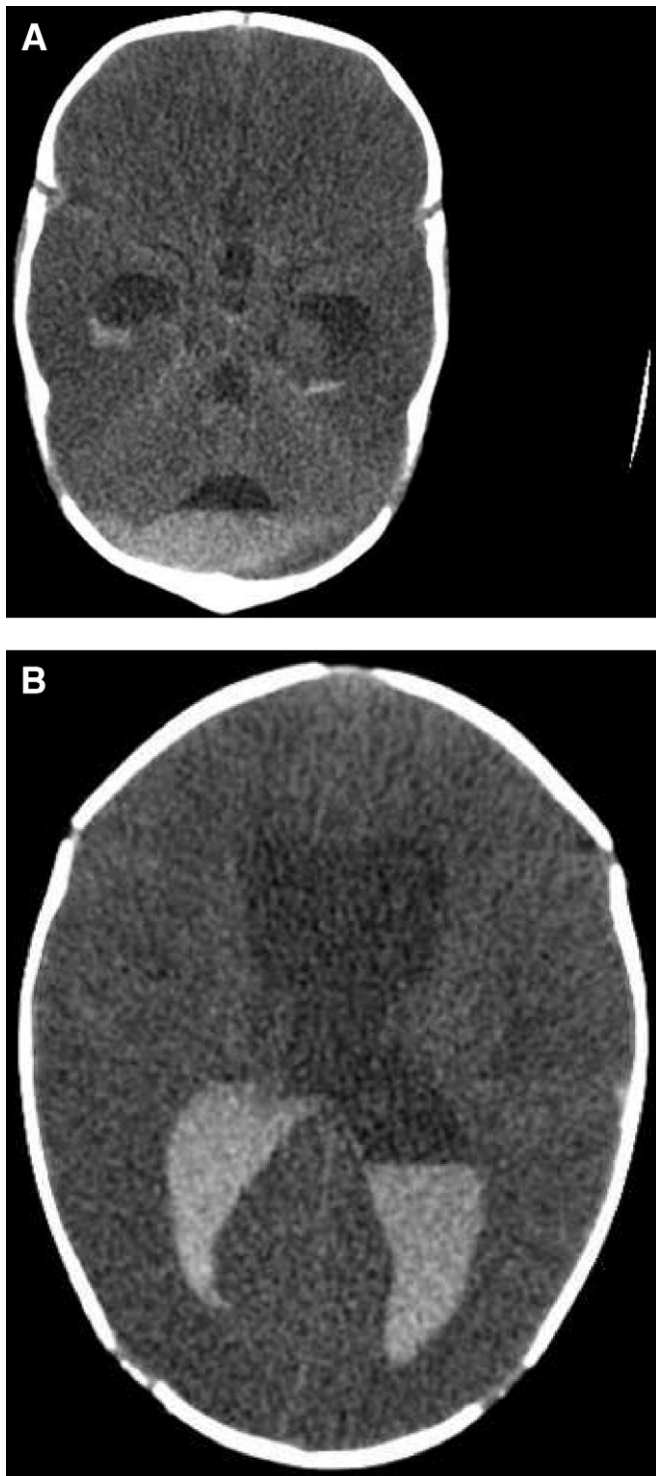


Figure. A, B, Head CT showed intraventricular hemorrhages, diffuse cerebral edema, and loss of the gray-white matter interphase.

The medical examiner declined the case after reviewing the medical record. The final autopsy report included intraventricular and subarachnoid hemorrhage of the brain, multiple ecchymoses, right upper lobe pleural petechial hemorrhages, focal mesenteric hemorrhages, and hepatosplenomegaly due to marked congestion. Additional studies revealed findings consistent with VKDB (Table).

Table. Laboratory findings

Laboratory value	Result (normal range)
Factor VII antigen level	74% (50% to 150%)
Factor VII procoagulant activity	< 1% (40% to 200%)
PIVKA	> 3860 ng/mL (< 3.6 ng/mL)
Factor VIII procoagulant activity	71% (55% to 180%)

DISCUSSION

VKDB may present with severe disease, such as intracranial hemorrhage, gastrointestinal bleeding, or any other form of internal hemorrhage.³ “Warning bleeds,” such as skin ecchymoses, umbilical oozing, or prolonged bleeding from circumcision, may occur and necessitate prompt investigation.⁶ Laboratory findings in VKDB include prolonged prothrombin time and partial thromboplastin time; decreased factor II, VII, IX, and X coagulant activity (the functional measure); and elevated PIVKA levels. Thrombin time; fibrinogen level; platelet count; factor II, VII, IX, and X antigen levels; and non-vitamin K-dependent factor V, VIII, XI, and XII coagulant activity are normal.¹ Without vitamin K administration at birth, the incidence of VKDB is 5 to 7 per 100 000 live births in Europe and Asia.^{4,5} Between 30% and 60% of cases are associated with intracranial hemorrhage, which can be fatal or result in devastating neurologic sequelae.⁶

Fortunately, VKDB is rare in countries in which parenteral vitamin K is administered at birth. According to Texas vital statistics data, between 1990 and 2004, 2 deaths occurred in Texas in which the underlying cause of death was VKDB (ICD-9 code 776.0). Based on the available data, we could not determine whether or not these 2 infants had been delivered by apprentice midwives. During that time period, a total of 66 607 infants were born to apprentice midwives in the state of Texas. Although the rate of VKDB seems low for the number of infants at risk, we cannot determine how many infants were exclusively breast-fed, received vitamin K through some other means (such as a pediatrician), or returned to Mexico after the birth, as our patient’s family had done.

The legal status of midwives varies widely across different states in the United States.⁷ A “lay” midwife (also known as a direct-entry, apprentice, or licensed midwife) practices in the home and has received no training in a formal program at an educational institution.⁷ According to the Texas Midwifery Board’s regulations, these practitioners are allowed to provide oxygen and eye prophylaxis but do not have prescriptive authority to administer any other medications, including parenteral vitamin K, to newborns. Furthermore, there is no requirement to inform the parents of the importance of parenteral vitamin K for preventing VKDB. In contrast, in Texas, a certified nurse midwife (CNM) is a registered nurse who has received additional training and certification in midwifery, is allowed to practice in a hospital setting, and has limited prescriptive authority.⁷ CNMs are regulated by the Texas State Board of Nurse Examiners.

To prevent other deaths like that of the patient reported here, we recommend that all Texas apprentice midwives either be required to inform parents (in writing, in their native language) of the risks of VKDB and the importance of prompt parenteral vitamin K administration in their infant or be given limited prescriptive authority to administer parenteral vitamin K. Although the number of infants delivered in Texas by apprentice midwives is relatively low, the loss of a healthy child to a preventable disease is tragic.

We thank Janice Jackson, Texas Department of State Health Services, Center for Health Statistics for the vital statistics data.

REFERENCES

1. Lane P, Hathaway W. Vitamin K in infancy. *J Pediatr* 1985;106:351-9.
2. Rutty G, Wolley A, Brookfield C, Sheperd F, Kitchen S. The PIVKA II test: the first reliable coagulation test for autopsy investigations. *Int J Legal Med* 2003;117:143-8.
3. Zipursky A. Prevention of vitamin K deficiency bleeding in newborns. *Br J Haematol* 1999;104:430-7.
4. American Academy of Pediatrics, Committee on the Fetus and Newborn. Controversies concerning vitamin K and the newborn. *Pediatrics* 2003;112:191-2.
5. Cornelissen M, von Kries R, Loughnan P, Schubiger G. Prevention of vitamin K deficiency bleeding: efficacy of different multiple oral doses schedules of vitamin K. *Eur J Pediatr* 1997;156:126-30.
6. Sutor A, von Kries R, Cornellsen M, McNinch A, Andrew M. Vitamin K deficiency bleeding in infancy. *J Thromb Haemost* 1999;81:456-61.
7. Butter I, Kay B. State laws and the practice of lay midwives. *Am J Public Health* 1988;78:1161-9.